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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/047,253	01/14/2002	Gregory Cope	CIT1510-4	6270

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EXAMINER

PAK, YONG D

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 06/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/047,253

Applicant(s)

COPE ET AL.

Examiner

Yong D Pak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-71 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-71 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

DETAILED ACTION

Claims 1-71 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-11, drawn to a polypeptide comprising a JAM domain, classified in class 435, subclass 183.
- II. Claims 12-14, drawn to a monoclonal antibody against the polypeptide of Invention I, classified in class 530, subclass 387.9.
- III. Claims 15-20, a method of identifying an inhibitor of using the polypeptide of Invention I, classified in class 435, subclass 4.
- IV. Claims 21-30, drawn to a method of deconjugating a modifier protein using the polypeptide of Invention I in vitro, classified in class 435, subclass 4.
- V. Claims 21-29 and 31, drawn to a method of deconjugating a modifier protein using the polypeptide of Invention I in vivo, classified in class 435, subclass 325.
- VI. Claims 32-57, drawn to a method of screening for an agent that affects deconjugation with the polypeptide of Invention I, classified in class 435, subclass 4.
- VII. Claim 58, drawn to a composition comprising the agent identified by Invention III, classified in class 514, subclass 789.

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- VIII. Claims 59-60, drawn to composition comprising the agent identified by Invention VI, classified in class 514, subclass 789.
- IX. Claims 61-70, drawn to a method of increasing conjugation with the polypeptide of Invention I, classified in class 435, subclass 4.
- X. Claim 71, drawn to a method of treating a condition with the agent identified by Invention VI, classified in class 514, subclass 789.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-II and VII-VIII are patentably distinct because a protein, an antibody, an inhibitor and an agent that affects deconjugation are different compounds, each with its own chemical structure and function, and they have different utilities. The structure of an antibody of Invention III is not predictable from the structure of the protein of Invention II and an antibody can cross-react with various proteins.

Inventions I and (III-VI and IX) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein of Invention I can be used for the production of antibodies against the protein.

Inventions VIII and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

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process of using that product (MPEP § 806.05(h)). In the instant case, the conditions listed in claim 71 can be treated with various over the counter medications.

The methods of Inventions (III-VI and IX) and X are patentably distinct as directed to materially different methods employing different products. Inventions III-VI and IX use polypeptides and Invention X uses an agent that affect deconjugation.

Inventions III-VI and IX are patentably distinct because the methods have different effects and utilizes.

In addition to election one of the patentably distinct inventions of I-X, applicants are required to further elect ONE patentably distinct polypeptide comprising the JAM domain having ONE patentably distinct JAM domain activity. The disclosure contains many polypeptides having different structure and function/substrate specificity. Also, applicants are required to further elect ONE target protein and ONE modifier protein. An example of a suitable election is a COP9/signalosome having a JAM domain having peptidase activity wherein the target protein is a Cul1 and the modifier protein is a NEDD8.

This is not an election of species. The different polypeptides comprising the JAM domain are patentably distinct inventions.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).


Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on 8:00 A.M. to 4:30 P.M weekdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong Pak
Patent Examiner



YONG PAK
Patent Examiner
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